

REMARKS

Claims 1-8, 14-16, 18, 19 and 32-35 are all the claims pending in the application. No claim amendments have been made.

I. Claim rejections under 35 U.S.C. § 102(e)

The Office Action of 12 January 2007 rejected claims 1-5, 7, 8, 18, 19 and 32-35 under 35 U.S.C. § 102(e) as allegedly anticipated by Schultz (US 6,180,415). Applicants respectfully disagree and traverse these arguments. As an initial matter, Applicants note that Schultz does not qualify as prior art under 35 U.S.C. § 102(e). Nevertheless, Applicants offer the following comments in response to the Office Action of 12 January 2007.

Regarding claims 1, 2 and 32, the Office Action alleges that “Schultz discloses determination of a dynamic property of a fluid volume (col. 45 lines 46-55).” *Office Action of 12 January 2007*, page 2. Applicants respectfully disagree. According to the specification of the claimed invention, dynamic properties include, but are not limited to, flow rate, mixing, distribution of a material during drying, distribution and/or number of function molecules or components, stability of material on a surface, the presence of flow features such as turbulence or micro eddies or other extremely local flow dynamic effects. While the Office Action alleges that Schultz discloses a method for determining flow, at most the only disclosure in Schultz to which the Office Action points is the use of PREs to observe the “motion” of an entity (e.g. red blood cells). *United States Patent No. 6,180,415, col. 45, ll. 46-55*. This disclosure however, does not amount to an anticipatory teaching of a method for using PREs to measure a dynamic property of a fluid. In particular, the reference fails to teach measuring a fluid property using resonance light scattering particles that are not specifically bound to another entity. The Office Action alleges that Schultz discloses a method for determination of a dynamic property wherein the light scattering particles are not bound to another entity by pointing to a passing reference within Schultz indicating that the PREs in Schultz may be “otherwise distributed” (*United States Patent No. 6,180,415, col. 8, ll. 40*) within a target. This passing reference, however, does not amount to an anticipatory teaching of resonance particles being distributed within a fluid. Indeed,

to anticipate a claim, a reference must teach each and every limitation of the claimed invention. Thus, Schultz does not teach each and every limitation of the claimed invention. Accordingly, Schultz does not anticipate claim 1, 2 and 32.

The Office Action also alleges that Schultz anticipates claim 3 by disclosing that the “dynamic property determined is particle distribution in the fluid volume (col. 9 line 23).” *Office Action of 12 January 2007*, page 3. As mentioned above, Applicants respectfully disagree and assert that the method of Shultz does not anticipate the claimed invention because the reference fails to teach a method for directly measuring particle distribution in a fluid volume without the use of an additional entity. Indeed, the passage upon which the Office Action relies is, once again, a passing reference to the “spatial distribution of a selected type of target binding sites...” *United States Patent No. 6,180,415, col. 9, ll. 23-24*. Accordingly, Schultz does not anticipate claim 3.

Regarding claims 4 and 5, the Office Action alleges that “Schultz discloses probes that are present in the fluid volume and the particle distribution is indicative of the distribution of the probes in the fluid volume (col. 9 line 24). The particles attached to a bonding site act as a probe in the fluid volume.” *Office Action of 12 January 2007*, page 3. Applicants assert that particles attached to a target bonding site cannot “act as a probe” in the fluid volume and thus Schultz cannot anticipate claim 4. The limitations of claim 1, inclusive in claim 4, mandate that the light scattering particles are not specifically bound to another entity. Thus, the Office Action disregards the limitations of claim 1, which are also present in claims 4 and 5, that specifically preclude the analysis of light scattering particles that are bound to other entities, such as target binding sites. Accordingly, Schultz does not anticipate claims 4 and 5.

Regarding claims 7 and 35, the Office Action alleges that “Schultz discloses the dynamic property is a flow pattern in a device or portion of a device, the device being an article of manufacture including one or more channels or reservoirs for fluid (col. 45 lines 50-55).” *Office Action of 12 January 2007*, page 3. Applicants point out that claims 7 and 35, dependent upon claims 1 and 32, respectively, are directed towards methods determining flow pattern in a device or portion of a device, “*wherein said at least one resonance light scattering particle is not*

specifically bound to another entity” (emphasis added). The passage upon which the Office Action relies discloses a method for observing the flow pattern of an analyte (red blood cells) in solution, by monitoring PREs that are bound to an analyte (*see* United States Patent No. 6,180,415, col. 45, ll. 50-55). The cited passage does not teach a method to determine the flow pattern of a fluid volume wherein the light scattering particles are specifically not bound to an analyte or entity within the fluid volume. Accordingly, Schultz does not anticipate claims 7 and 35.

Regarding claim 8, the Office Action alleges that “Schultz discloses the dynamic property is fluid mixing being evaluated in one or more portions of the device or through the entire device, the portions being selected from the group consisting of a mixing chamber, a port, a flow channel, a pump, a valve, and a flow channel intersection (col. 49 lines 56-65).” *Office Action of 12 January 2007*, page 3. Applicants respectfully disagree and assert that Schultz fails to teach a method for determining fluid mixing. At best, Schultz suggests the use of PREs to label cells within a pre-existing mixed population of cells. Thus, complete mixing has already occurred before the addition of PREs to the field, precluding the evaluation of fluid mixing. Indeed, the passage upon which the Examiner relies states that “[a] mixed cell population is analyzed for one cell type expressing a particular surface antigen using a particular PRE probe. In addition, several cell types are isolated by simultaneously using multiple PRE probes because of the number of uniquely identifiable PRE probes with distinct spectral signatures that can be made.” *United States Patent No. 6,180,415, col. 49, ll. 56-65*. Thus, a cell sorting sample consists of a mixture of targets (cells), rather than a mixture of fluid volumes. Furthermore, the passage demonstrates that the PREs in Schultz are used to isolate analytes within a mixture, rather than determine mixing properties of a fluid. Thus, Schultz fails to disclose a method wherein fluid mixing is evaluated. Accordingly, Schultz fails to anticipate claim 8.

Regarding claims 18, 33 and 34, the Office Action alleges that “Schultz discloses the at least one resonance light scattering particle comprises a plurality of distinguishable resonance light scattering particles (col. 49 lines 56-65).” *Office Action of 12 January 2007*, page 4. Applicants respectfully disagree and assert that Schultz fails to teach each and every element of

the claims. Applicants assert that claims 18, 33 and 34 refer to a method for determining a dynamic property (claim 18), such as flow pattern (claims 33 and 34), using a plurality of different resonance light scattering particles, *wherein said at least one resonance light scattering particle is not specifically bound to another entity* (emphasis added). Similar to the discussion above, the passage upon which the Office Action relies, at best, demonstrates the use of multiple PRE probes to label cells within a pre-existing mixed population of cells. Accordingly, Schultz does not anticipate claims 18, 33 and 34.

Regarding claims 8, 18, 19, 33 and 34, the Office Action alleges that “Schultz discloses the plurality of distinguishable resonance light scattering particles is used to analyze mixing of fluids from two different sources (col. 49 lines 56-65).” *Office Action of 12 January 2007*, page 4. Applicants respectfully disagree and assert that Schultz does not teach one skilled in the art a method to analyze mixing of fluids from two different sources. It is well known in the art that the method of cell sorting is for the purpose of isolating cells from a pre-existing mixed population of cells. Consistent with this, Schultz states that “[a] mixed cell population is analyzed for one cell type expressing a particular surface antigen using a particular PRE probe. In addition, several cell types are isolated by simultaneously using multiple PRE probes because of the number of uniquely identifiable PRE probes with distinct spectral signatures that can be made” *United States Patent No. 6,180,415, col. 49, ll. 56-62*. Furthermore, Applicants respectfully disagree with the Office Action’s assertion that “[t]he different cells disclosed in Schultz are equivalent to different fluids ... [t]he term fluid is defined as tending to flow or conform to the outline of its container. Animal cells conform to the outline of their container due to their flexible outer membrane and mostly liquid interior.” *Office Action of 12 January 2007*, page 4. Applicants assert that the cell populations disclosed by Schultz represent the target rather than the fluid volume. In addition, Applicants contend that animal cells are not the equivalent of fluid and do not inherently conform to the outline of their container. Indeed, animal cells comprise an extensive cytoskeletal network of actin and tubulin microfilaments which impart considerable structural rigidity and regulate cell shape and morphology. Applicants assert that since different animal cell types have markedly different morphologies (spherical, e.g. lymphocytes; spindle

shaped, e.g. fibroblasts; long and tapering, e.g. non-striated muscle cells), animal cells cannot simply “conform to the outline of their container”, otherwise such cell-type specific morphologies, which are well known in the art, would not exist. Indeed, the Office is reminded that claim terms are to be given their common and ordinary meaning (*see* MPEP 2111.01).

Even if all the elements of the presently claimed invention are present in Schultz, which the Applicants contest, Applicants assert that Schultz does not anticipate the claimed invention because Schultz does not represent an enabling disclosure. Passing references to elements of the claims in a publication do not constitute an enabling disclosure for anticipation purposes. Indeed, “the identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Further, Federal Circuit precedent makes it clear that an anticipating reference must “sufficiently describe the claimed invention to have placed the public in possession of it.” *In re Donohue* 766 F.2d 531, 533 (Fed. Cir. 1985). Schultz does not enable the claimed invention because Schultz does not disclose “the identical invention ... in as complete detail as is contained in the ... claim”, thus Schultz cannot anticipate the claimed invention. Specifically, Schultz does not teach how to use unbound resonance light particles to measure fluid dynamics. As stated previously, a passing reference to particles that are “otherwise distributed” (*United States Patent No. 6,180,415, col. 8, ll. 40*) cannot be considered a specific teaching to put the public in possession of a method of measuring fluid dynamics using unbound particles. In addition, Schultz provides no specific disclosure, let alone an enabling teaching, regarding the specific dynamic properties disclosed and claimed in the present invention. Indeed, Schultz does not disclose any teaching regarding fluid dynamics. At most, Schultz discloses monitoring cell movement within a fluid. A suggestion of monitoring cell movement, however, can not be used to teach the public how to use light scattering particles to measure fluid dynamics.

Accordingly, Schultz cannot anticipate the Applicants claimed invention. Applicants request reconsideration and withdrawal of the outstanding anticipation rejection.

II. Claim rejections under 35 U.S.C. § 103(a)

The Office Action of 12 January 2007 rejected claim 6 under 35 U.S.C. 103(a) as allegedly being unpatentable over Schultz (US 6,180,415) in view of Tateiwa (US 5,444,529). Applicants respectfully disagree with the allegations of the January 12th Office Action and request that the Examiner reconsider and withdraw the obviousness rejection in view of the remarks below.

To establish a *prima facie* case of obviousness, three criteria must be established. First, the references must teach each and every limitation of the currently claimed invention, *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974). Second, the Office must provide sufficient reasons why one of skill in the art would combine the references to arrive at the claimed invention. Finally, there must be a reasonable expectation of success in combining the references, and this expectation of success must also be found in the references as well. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

The Office Action alleges that “Schultz teaches the invention as claimed but lacks specific reference to drying.” *Office Action of 12 January 2007*, page 4. As discussed above, Schultz fails to disclose each and every limitation of the presently claimed invention. The Office Action points to a passing reference within Schultz indicating that PREs may be “otherwise distributed” (*United States Patent No. 6,180,415, col. 8, ll. 40*) within a target. Further, Schultz does not teach how to measure any sort of dynamic property of a fluid. Thus, Schultz does not teach each and every limitation of the claimed invention.

The Office Action then cites Tateiwa for the proposition that “Tateiwa teaches that the light source incident upon the fluid sample will cause the fluid to evaporate, thus the fluid would dry on the surface (col. 2 lines 11-27).” *Office Action of 12 January 2007*, page 4. The Office Action then concludes that “it would have been obvious to one of ordinary skill in the art at the time the invention was made that the light source of Schultz could perform the same evaporative function as the light source in Tateiwa for the purpose of determining the surface tension of the fluid by the size and shape of the portions of fluid as the surrounding fluid evaporates.” *Office Action of 12 January 2007*, pages 4-5. Applicants respectfully assert that Tateiwa fails to teach

one skilled in the art that the “light source incident upon the fluid sample will cause the fluid to evaporate.” *Office Action of 12 January 2007*, page 4. Rather, Tateiwa teaches the opposite, in that lowering of the temperature of the silicon substrate leads to condensation of water molecules around a dust particle. Upon irradiation of the silicon substrate with a laser light source, the “irregular reflection light patterns reflected therefrom are detected by the light detector.” *United States Patent No. 5,444,529, col. 2, ll. 38-51*. Thus, one skilled in the art would understand Tateiwa to teach that the laser light source does not result in fluid evaporation, since evaporation would negate determination of light scattering by condensed water droplets. Thus, Tateiwa cannot be cited for the proposition that a light source must necessarily be equal to fluid evaporation. Accordingly, the combination of Schultz and Tateiwa fails to disclose each and every element of the claimed invention, and one skilled in the art could not arrive at a method for the claimed invention by combining these two references.

Furthermore, Applicants assert that the Office Action has not provided sufficient reasons as to why one of skill in the art would combine the teachings of the references. Applicants also assert that one of ordinary skill in the art would not be compelled to combine the references to arrive at the claimed invention since, at best, the two references analyze different types of light scattering produced by unrelated mechanisms. Shultz specifically discloses the interrogation of a target by the binding of entities that exhibit plasmon resonance, whereas Tateiwa discloses the detection of pre-existing dust particles by condensing water droplets on the dust particle and determining optical light scattering by the water droplets. Thus, Applicants assert that no one would combine Tateiwa and Schultz to arrive at the claimed invention, because the references do not relate to one another in their use of light. Considering the lack of relatedness of the cited references and that the Office has failed to provide sufficient basis as to why one of skill in the art would combine the references, the Office fails to establish a *prima facie* case of obviousness over the cited references..

The Office action rejected claims 14-16 under 35 U.S.C. 103(a) as being unpatentable over Schultz (US 6,180,415). The Office Action asserts that “Schultz teaches the invention as claimed but lacks reference to specific volumes. Schultz does state that individual cells and

groups of cells can be examined by the same device (col. 45 lines 22-49). Cells are known to have volumes within the claimed ranges. For example, white blood cells have volumes on the order of a nanoliter (nL) and red blood cells have volumes on the order of a picoliter (pL). One might examine a single cell to observe cell division (Schultz, col. 45 line 26). One might examine a larger quantity of cells to observe cells in circulation (Schultz, col. 45 line 45). Therefore the number of cells examined determines the volume of fluid in the device.” *Office Action of 12 January 2007*, page 5. Applicants assert that animal cells do not conform to the outline of their container, and thus are not equivalent to fluids, for the reasons outlined in the response to the rejection of claim 19. Moreover, the applicants argue that the animal cells in Schultz correspond to a target rather than a fluid volume. Applicants request reconsideration and withdrawal of the remaining obviousness rejections.

III. Conclusion

Applicants have made no claim amendments and have traversed the remaining rejections over the claims. Applicants request reconsideration and withdrawal of the anticipation and obviousness rejections. Should the Examiner believe that further discussion of any remaining issues would advance the prosecution, he or she is invited to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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